# SJ-EXHIBIT 42

# National Association of Boards of Pharmacy

Testimony
before the
Senate Committee on the Judiciary

Oversight of the Ensuring Patient Access and Effective Drug Enforcement Act

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Good Morning Chairperson Grassley, Ranking Member Feinstein, and Members of the Senate Committee on the Judiciary. I am Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy (NABP). Thank you for the opportunity to inform the Committee of the critical importance of repealing or modifying the Ensuring Patient Access and Effective Drug Enforcement Act (EPAEDEA). NABP represents all 50 United States, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, Australia, Bahamas, and 10 Canadian provinces. NABP's purpose is to assist the state boards of pharmacy with their legislative mandate to protect the public health.

NABP maintains, and has steadfastly done so since September 5, 2014 in letters to Senators Grassley and Leahy, that the intent of the EPAEDEA was to significantly decrease the DEA's enforcement authority. In those September 5, 2014 letters to Senators Grassley and Leahy (attached), NABP specifically commented that the EPAEDEA would have a:

> "… detrimental impact on the protection of the public health and irreparable damage to the enforcement ability and authority of Drug Enforcement Administration (DEA). A crippling of this authority will significantly hamper efforts of DEA and state boards of pharmacy to combat the epidemic of drug abuse and diversion that has inflicted injury and death on citizens in every state across the US."

The EPAEDEA feigns to offer avenues to increase communications with the DEA, support enforcement, and ultimately ensure the uninterrupted delivery of controlled substances. Despite how it has been characterized and rationalized by supporters, the fact of the matter is that the law simply, effectively, and intentionally curtails the enforcement authority of the DEA. In fact, DEA Chief Administrative Law Judge John J. Mulrooney II described a major consequence of the EPAEDEA by noting that "before the DEA can proceed to secure an administrative sanction against a registration holder or deny an application for registration, it must now consider a written improvement plan, filed by the registrant or applicant, which outlines that registrant or applicant's intentions to correct the regulatory transgressions alleged in the order to show cause.[1]

Mulrooney went even farther to identify the impact of changes in the DEA's enforcement authority imposed by the EPAEDEA's corrective plan requirements: "the EPAEDEA's CAP provisions create no incentive (and potentially a disincentive) for regulated companies or individuals to self-report … violations, to correct wrongdoing before an OSC is filed or even to follow or continue following whatever plan is deemed sufficient to discontinue or defer proceedings once the proceedings are discontinued or deferred."[2]

[1] Mulrooney II, John J. & Legel, Katherine E. Current Navigation Points in Drug Diversion Law: Hidden Rocks in Shallow, Murky, Drug Infested Waters. Marquette Law Review, Vol. 101.
[2] Ibid

NABP concurs with Judge Mulrooney's conclusions regarding the EPAEDEA's deliberate restrictions on the DEA's ability to act because of the imposition of corrective action plans. In our September 5, 2014 correspondence, we stated: "When an imminent danger to the public health exists, there is no reasonable time period for corrective action and no acceptable action except the ceasing of activities through the DEA's authority to revoke or suspend a registration. Further, affording a registrant engaged in activities so egregious that they constitute an imminent danger to the public health a period of time to submit a corrective action plan in lieu of suspension or revocation, allows such activities to continue virtually unfettered by simply accepting the assurances of a registrant that has already engaged in such egregious activity at the onset."

The ability to act decisively when an imminent danger to the public health or safety exists is critical to protecting the public health. It is an enforcement action legislatively mandated to the state boards of pharmacy and utilized repeatedly and effectively by the state boards of pharmacy. Proponents of the EPAEDEA maintained that the absence of a clear definition of imminent danger to the public health and safety was a primary factor for excessive enforcement actions by the DEA and the subsequent negative impact on patient access to controlled substances. From NABP's perspective, based upon state definitions and actions in situations that constitute an imminent danger to the public health or safety, there appeared to be little if any regulatory need for the EPAEDEA to define imminent danger to the public health and safety beyond what existed prior to the enactment of the law. State boards of pharmacy rely on the determination of imminent danger to the public health or safety to cease operations or deny licensure/registration for pharmacists, pharmacies, wholesale distributors and other entities. Situations that constitute an imminent danger to the public health and safety are defined similarly in state practice acts and regulations as was defined in the Controlled Substances Act and Regulations prior to the enactment of the EPAEDEA. The defining of imminent danger to the public health or safety by the EPAEDEA is confusing from the perspective of state regulatory agencies that successfully utilize provisions once contained in the Controlled Substances Act and Regulations to act with expediency and in the foremost interest of the public protection. The change to define "imminent danger to the public health or safety" in the Controlled Substances Act and Regulations by the enactment of the EPAEDEA, in light of the continued successful utilization by the states of regulatory language and authority similar to what existed before the enactment of the EPAEDEA, speaks less to the need for such a change for enhanced regulatory purposes as it does to other considerations or interests desiring to change or diminish the authority of the DEA.

As an expert witness for the DEA and US attorney offices across the states, I can also personally attest that the cases I have assisted with were unequivocal instances of egregious activities by wholesale distributors, pharmacists, and prescribers that threatened the public health and were ultimately responsible for the deaths of patients. In one of the cases, the imminent danger that existed was the actual overdose and death of 14 people, some of whom were from the same family, as a result of the distribution and dispensing of controlled substances to one pharmacy. The restriction of the DEA's ability to take immediate action until consideration of a corrective action plan in this and the other cases that I assisted with would have only resulted in more patients being harmed or dying from drug diversion and overdoses. In these cases, the

access to controlled substances for legitimate medical purposes was not an issue and would not have been interrupted. The delaying of DEA actions would only have served to advance the activities of the principals involved in the illegal diversion of controlled substances. The principals involved in these cases were afforded multiple opportunities to correct their actions through direct interactions with the DEA or state boards of pharmacy prior to the situation escalating to an imminent danger to the public health and safety. In response to these "communications" the principals chose not to correct their actions or become compliant, ignored the multiple discussions and warnings from the DEA and other regulatory agencies such as the boards of pharmacy, and continued to distribute and dispense medications that took the lives of more patients. Fortunately, the cases and situations just described represent the minority of practitioners. NABP, in unison with the states, has accredited nearly 700 wholesale distributors through our Verified Wholesale Distributor Program (VAWD). Through the VAWD program we have come to better understand the wholesale distributor industry. Our collaborative efforts with the states and the significant number of wholesale distributors who have become accredited allow us to confidently represent that those wholesale distributors who achieve accreditation have processes in place to comply with the Controlled Substances Act and Regulations and are determined to be compliant with all federal and state laws.

As an additional consequence of the enactment of the EPAEDEA that bears further consideration is "suspicious orders." Supporters of the EPAEDEA argued that the Controlled Substances Act and Regulations and guidance issued by the DEA lacked clarity as to what constituted a suspicious order placing the wholesale distributor industry in a perplexing and non-compliant situation. Once again, in the cases that I have been involved in as an expert witness, there was no question as to what constituted a "suspicious order." The only question that existed was why the wholesale distributor continued to distribute controlled substances to the pharmacy, prescriber, or clinic when the evidence of "suspicious orders" was so readily apparent. State boards of pharmacy, many of which require the reporting of suspicious orders, consistently convey to NABP that the reporting of suspicious orders to them is simply an obfuscation of information and attempt to bury the state boards of pharmacy in meaningless paperwork. Reports of suspicious orders are sent to state boards of pharmacy in a variety of formats and based upon a variety of circumstances. In the situations reported to NABP by the state boards of pharmacy, the reporting entity makes no effort to distinguish a legitimate suspicious order and simply declares every situation, even the one-time damage of a single container of 30 tablets of a controlled substance, as a "suspicious order." The reporting seems to be nothing more than a statement to the boards of pharmacy saying, *we have complied with the reporting of "suspicious orders" by reporting everything and anything, now you figure it out!*

NABP's VAWD program and the accreditation of wholesale distributors speaks loudly to the collaboration that occurs between the wholesale industry and state regulators and has helped stakeholders better understand what constitutes a suspicious order and the due diligence that must occur as the result of a suspicious order. It is one of the foundational areas that NABP's VAWD program identifies and works with wholesale distributors to address and correct, if necessary. To further these collaborative efforts NABP is in discussion with states on how to more clearly define "suspicious orders" and standardize the reporting. This is an area that NABP

believes should be addressed through federal legislation if the EPAEDEA is repealed or modified.

NABP also works collaboratively with a wide spectrum of stakeholders and state and federal government representatives on innovative solutions to fight the opioid epidemic. In 2011, NABP established PMP InterConnect, which today is a nation-wide network of prescription drug monitoring programs that enables sharing of data across state lines. This tool, which NABP provides at no cost to the states, currently has 42 states connected and will have 45 states connected in early January. PMP InterConnect is also being used to integrate PMP data into the clinical workflow of physicians and pharmacists in 31 states. In 2013, NABP convened a coalition of stakeholders to develop a consensus document to establish "red flag" warning signs related to prescribing and dispensing of controlled substance prescriptions, which was released in 2015.

In closing, NABP appreciates the opportunity to appear at this hearing today. We offer our assistance to the Committee and strongly urge the repeal or extensive modification of the Ensuring Patient Access and Effective Drug Enforcement Act.